

Poster presentation

Effect of a fixed-dose combination of emtricitabine, tenofovir and efavirenz on adherence and treatment acceptability (ADONE study)

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Purpose of the study

Aim of the ADONE study was to verify the effect of a reduced number of pills on adherence and HAART acceptability.

Methods

ADONE is a prospective, multicenter study in patients chronically treated with FTC+TDF+EFV or 3TC+TDF+EFV, showing a stable viremia <50 copies/ml. At baseline, patients substituted their HAART with a fixed-dose combination (FDC) of FTC+TDF+EFV. Data were collected by means of a modified ACTG questionnaire. To collect the answers a visual analogue scale based on a horizontal line of 100 mm was used. For each item patients were asked to scale themselves from 0–100. The study is ongoing and planned to complete 6-months follow-up. A planned preliminary analysis according to the intention-to-treat approach is reported.

Summary of results

A total of 203 patients (159 males and 44 females) with a mean age of 46.3 years (SD 10.0) were enrolled. At baseline all patients had a viral load below the limit of detection and the mean CD4 count was 564 cells/mcL (SD 250). The simple reduction of the number of pills, induced a statistically significant ($p = 0.014$) increment of self-reported adherence (number of doses assumed over the previous month) from the mean baseline value of

96.1% (95% CI 94.3–97.9) to 97.7% (95% CI 97.0–98.4). Similarly the number of doses assumed full-filling scheduled timing (+/- 1 hour) increased from 92.9% (95% CI 90.4–95.4) to 96.0% (95% CI 94.8–97.2) ($p = 0.033$). A marked increment of treatment acceptability ($p < 0.0001$ for all items) was also observed after therapeutic switch (Figure 1). All patients maintained HIV-RNA <50 copies/ml.

Conclusion

The ADONE study is the first clinical experience exploring the effect on adherence of a simplification strategy based on the reduction of pills without a substantial change of the drugs included into the therapeutic regimen. Its primary endpoints are adherence, acceptability of HAART and quality of life of patients. By simply using a FDC, one pill once-a-day, we obtained an improvement of self-reported adherence. Furthermore, the patients' judgement about simplicity, convenience, tolerability and efficacy of the FDC was significantly more positive if compared with the use of the same drugs as single pills. The simplicity of the therapeutic regimen is an added value of HAART that increments adherence and may improve long-term success.

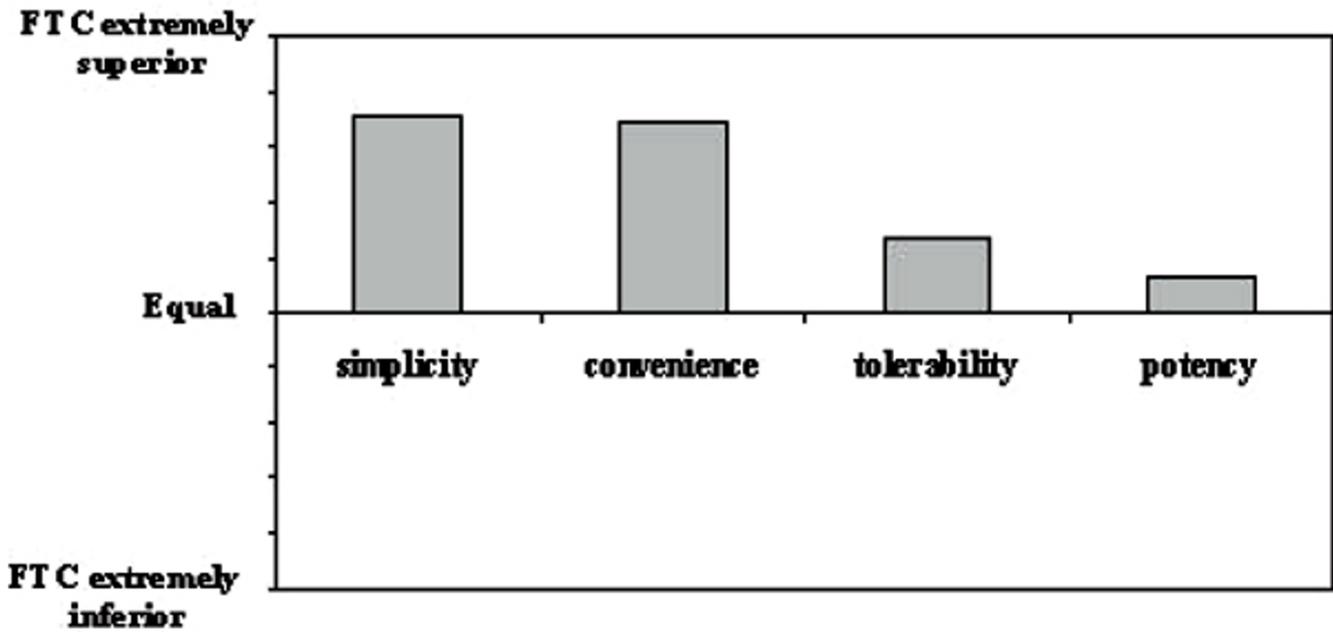


Figure 1

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